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09/602,740	06/23/2000	Markus Pompejus	BGI-126CP	1632

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EXAMINER
KERR, KATHLEEN M

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/602,740	Applicant(s) POMPEJUS ET AL.	
	Examiner Kathleen M Kerr	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 June 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-38* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Application Status

1. Claims 1-38 are pending in the instant application. The Notice to Comply mailed on July 16, 2001 (Paper No. 5) was in error. The amendment filed by Applicants on June 20, 2001 amended the sequence listing to effectively comply with the sequence rules.

Restriction

2. Restriction to one invention is required under 35 U.S.C. § 121. The SuperGroups below divide the inventions into general categories. The Groups, described below but not specifically delineated, identify the different inventions, one of which must be elected.

SuperGroup A: Claims 1-17 and 36-38, drawn to nucleic acid molecules, vectors, host cells, and methods of making a polypeptide, classified in class 435, subclass 183.

SuperGroup B: Claims 18-24, drawn to polypeptides, classified in class 435, subclass 183.

SuperGroup C: Claims 25-34, drawn to methods of making fine chemicals, classified in class 435, subclass 41.

SuperGroup D: Claim 35, drawn to methods for diagnosing the presence or activity of DNA sequences of *C. diphtheriae*, classified in 435, subclass, 6.

SuperGroup E: Claim 35, drawn to methods for diagnosing the presence or activity of protein sequences of *C. diphtheriae*, classified in 435, subclass, 7.1.

SPECIAL NOTE:

Each SuperGroup above is **further divided** into Groups related to each particular sequence (enzyme) claimed from Table 1. Due to the great number of individual sequences

identified and the minute differences between F-designated and non-F-designated (a single character), the Examiner will not particularly delineate the Groups individually since mistakes may be made and the number of inventions (Groups) may be incorrect.

For election purposes, Applicants must identify a Group (not just a SuperGroup) to be examined; this Group ***must be comprised*** of the following:

(1) a SuperGroup, as noted above, **and**

(2) a particular sequence (gene) from Table 1.

The different genes in Table 1 are ***not*** species of a single invention, but individual inventions (Groups) for the reasons cited below. Moreover, none of these different genes can be related to one another generically (to support the idea of their being species) except as genes from *C. glutamicum*; this "generic" characterization contains no structure and no function.

If this explanation of the restriction is *unclear* to Applicants, they are invited to contact the undersigned Examiner for clarification. A traversal of the restriction requirement, however, should be made of written record in response to this Office action.

3. The inventions are distinct, each from the other because of the following reasons. First, distinction among the SuperGroups will be demonstrated *followed by* distinction among all the different gene sequences in Table 1.

Distinction Among SuperGroups

The DNA of SuperGroup A is related to the enzymes of SuperGroup B by virtue of the fact that the DNA encode the enzymes in a one-to-one relationship; all other DNA:enzyme pairs are unrelated. The DNA molecule has utility for the recombinant production of the enzyme in a

host cell. Although the DNA and the enzyme are related, they are distinct inventions because the enzyme product can be made by other and materially distinct processes, such as purification from a natural source. Furthermore, DNA can be used for processes other than the production of enzyme, such as nucleic acid hybridization assays. Therefore, members of SuperGroups A and B are patentably distinct or unrelated.

The DNA of SuperGroup A is related to the methods of SuperGroup C as product and process of use. Each DNA Group of SuperGroup A is used in a distinct method Group of SuperGroup C. The below explanation of distinction is for DNA used in particular processes; all other pairs of Groups are unrelated. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the DNA can be used in a materially different process, such as in hybridization assays to identify functionally homologous genes in related organisms or methods of recombinantly producing the encoded polypeptide. Therefore, members of SuperGroups A and C are patentably distinct or unrelated.

The DNA of SuperGroup A is related to the methods of SuperGroup D as product and process of use. Each DNA Group of SuperGroup A is used in a distinct method Group of SuperGroup D. The below explanation of distinction is for DNA used in particular processes; all other pairs of Groups are unrelated. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a

materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the DNA can be used in a materially different process, such as in hybridization assays to identify functionally homologous genes in related organisms or methods of recombinantly producing the encoded polypeptide. Therefore, members of SuperGroups A and D are patentably distinct or unrelated.

SuperGroups A and E are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04, M.P.E.P. § 808.01). In the instant case, the DNA is not disclosed as being used in the methods of SuperGroup E; said methods would utilize antibodies or some other means of specific protein identification. Thus, SuperGroups A and E are patentably distinct.

SuperGroups B and C are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04, M.P.E.P. § 808.01). In the instant case, the polypeptides are not disclosed as being used in the methods of SuperGroup C. Said methods utilize the encoding DNA in host cells acting as miniature chemical production plants, but the isolated polypeptides are not utilized. Thus, SuperGroups B and C are patentably distinct.

SuperGroups B and D are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04, M.P.E.P. § 808.01). In the instant case, the polypeptides are not disclosed as being used in the methods of SuperGroup D; said methods

utilize the encoding DNA in, for example, hybridization assays. Thus, SuperGroups B and D are patentably distinct.

SuperGroups B and E are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04, M.P.E.P. § 808.01). In the instant case, the polypeptides are not disclosed as being used in the methods of SuperGroup E; said methods utilize, for example, antibodies, or some other protein-specific reagent, but not the isolated polypeptides themselves. Thus, SuperGroups B and E are patentably distinct.

The methods of SuperGroups C-E are related by virtue of the reagents used being similar and/or complementary (i.e., DNA to protein to antibodies). However, in each SuperGroup of methods, distinct method steps are used as evidenced by their distinct class/subclass classifications. Thus, SuperGroups C-E are patentably distinct, each from the other.

Distinction Among Groups within a SuperGroup

Each of the Groups, drawn to distinct gene sequences from Table 1, in SuperGroup A are distinct due to their structure and function. Clearly in Table 1, each gene is identified by a particular sequence and function of the encoded protein. The structures (sequences) of these DNA are not disclosed as being related by virtue of some consensus sequence or other factors; their relation comes only from their common source, *C. glutamicum*. The functions of these DNA are not disclosed as being related by virtue of encoding some enzymes of common pathways and/or mechanisms; again, their relation comes only from their common source, *C.*

glutamicum. Thus, being unrelated in structure and function, each gene sequence as identified in Table 1 is distinct from every other sequence.

Each of the Groups, drawn to distinct protein sequences from Table 1, in SuperGroup B is distinct due to their structure and function. Clearly in Table 1, each protein is identified by a particular sequence and catalytic function. The structures (sequences) of these proteins are not disclosed as being related by virtue of some consensus sequence or other factor; their relation comes only from their common source, *C. glutamicum*. The functions of these proteins are not disclosed as being related by virtue of some common pathway and/or mechanism; again, their relation comes only from their common source, *C. glutamicum*. Thus, being unrelated in structure and function, each protein sequence as identified in Table 1 is distinct from every other sequence. Moreover, many of the disclosed protein will be classified distinctly in view of their function (i.e., enzyme classification in the E.C. system).

The method groups within SuperGroups are distinct because they utilize different DNA sequences and/or proteins that are distinct for the reasons set forth for the distinct DNA and protein Groups.

Search Burden for Searching More than One SuperGroup

In addition to the distinctness of SuperGroups A and B, which are identically classified under U.S. Patent Classification guidelines, a combination of Groups from SuperGroups A and B would present a search burden due. For example, claims in SuperGroup B, drawn to polypeptides, must be searched not only in commercial amino acid sequence databases, but also in textual databases because isolated polypeptides are often disclosed without the benefit of

sequence information although the amino acid sequence is inherently the same as the sequence claimed. Additionally, the nucleic acid sequences of SuperGroup A must be searched in distinct nucleic acid sequence commercial databases. Thus, Groups in SuperGroups A and B have been appropriately restricted on the basis of being both independent or distinct and presenting a search burden on the Examiner.

Because some of these SuperGroups are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification (Groups from SuperGroups A and B from C, D, and E), restriction for examination purposes as indicated is proper.

Search Burden for Searching More than One Group within a SuperGroup

It would be unduly burdensome to examine any more than one DNA sequence disclosed together with other DNA sequences. Each of these searches is distinct and not co-extensive or even overlapping. Each of these searches must utilize valuable computer processing time as well as the Examiner's time in analyzing the results. Moreover, a text search using different keywords, such as the identified encoded enzyme in Table 1, is required for each distinct DNA sequence; these searches are also not co-extensive. The M.P.E.P. states that "up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction" (see M.P.E.P. 803.04). However, *any* DNA which encodes the disclosed polypeptides are claimed; the search for a specific nucleic acid sequence is different from the search for all possible nucleic acid sequences encoding a particular protein, even if that protein is encoded by the original nucleic acid sequence. The examination of *any one* exact DNA

sequence or any DNA encoding *any one* exact protein sequence must be searched to adequately search the claims, as written. This is a genus of DNA sequences that is many more than 10 individual sequences.

It would be unduly burdensome to examine any more than one protein sequence disclosed together with other protein sequences. Each of these searches is distinct and not co-extensive or even overlapping. Each of these searches must utilize valuable computer processing time as well as the Examiner's time in analyzing the results. Moreover, a text search using different keywords, such as the function of the enzyme in Table 1, is required for each distinct protein sequence; these searches are also not co-extensive.

Examining any two of the method groups together would present a search burden for the reasons set forth for the distinct DNA and protein searches.

Notice of Possible Rejoinder

4. The Examiner notes that if product claims of SuperGroup A are found directed to an allowable product, then related methods claims (using the particular, patentable DNA product) in SuperGroups C and D, which are directed to processes of using the patentable product, previously withdrawn from consideration as a result of a restriction requirement, would now be rejoined pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86; see also M.P.E.P. § 821.04, *In re* Ochiai, and *In re* Brouwer). Since process claims in SuperGroups C and D would be rejoined and fully examined for patentability under 37 C.F.R. § 1.104, Applicants are instructed to amend said claims as deemed necessary according to rejections made against the elected claims.

Election

5. A telephone call was made to Elizabeth Hanley on January 24, 2002 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. § 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(i).

Conclusion

6. A complete response to the instant written restriction must include an election of invention to be examined. Considering the language of the instant restriction requirement above, Applicants must identify a SuperGroup **and** a gene sequence to elect a single invention and be fully responsive.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229. The examiner can normally be reached on Monday through Friday, from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone

numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

KMK
January 26, 2002